UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge **Oral Argument Requested**

ZHP'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON THEIR FRAUD CLAIMS AGAINST ZHP

INTRODUCTION

Plaintiffs are asking the Court to usurp the role of the jury and grant them summary judgment on their fraud claims against ZHP based on a so-called "smoking gun email" from 2017 supposedly showing that ZHP knew of the potential for nitrosamine formation in its manufacturing processes. Plaintiffs' argument presupposes that there is no triable question as to the multiple other elements of their fraud claims, even though they have no evidence of reliance on any purportedly false misrepresentation or damages, as elaborated in Defendants' pending motion for summary judgment. In any event, the single email highlighted by Plaintiffs addresses a hypothetical nitrosated impurity in the lab-scale production of Irbesartan, a different drug molecule from Valsartan API. Given the dispute over the import of that email and bevy of other evidence showing that ZHP had no pre-2018 knowledge of the potential for nitrosamine formation in the VCDs, Plaintiffs' fraud claims should be decided by the jury in the event the Court denies Defendants' pending motion for summary judgment.

ARGUMENT

The standard governing a motion for summary judgment is set forth in the TPP Trial Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgment, incorporated herein. Despite material variations in the potentially applicable common-law fraud regimes, most states generally require proof of the

following five elements: (1) a materially false representation; (2) knowledge of its falsity; (3) an intention that the other party rely on it; (4) reasonable reliance on the purported fraud; and (5) resulting damages. (*See* Pls.' Br. at 4.) As courts have routinely recognized, these elements are generally not susceptible to resolution at summary judgment, which is presumably why Plaintiffs do not cite a single case granting a plaintiff summary judgment on such a cause of action. *See, e.g.*, *Siever v. BWGaskets, Inc.*, 669 F. Supp. 2d 1286, 1294-95 (M.D. Fla. 2009) (noting that "[a]s a general rule 'summary judgment [is] not appropriate to resolve a fraud claim under Florida law'" and denying summary judgment) (citation omitted); *In re Est. of Richmond*, 701 N.W.2d 897, 901 (N.D. 2005) (granting summary judgment ***against*** plaintiff on fraud claim despite noting that "fraud actions are not usually suited for disposition by summary judgment"). Although Plaintiffs claim that it "cannot be disputed" that each of these elements has been satisfied in this case, their arguments lack merit.

First, Plaintiffs argue that ZHP misrepresented that its valsartan was "Valsartan USDMF Grade API" because the product contained trace amounts of NDMA and NDEA, which Plaintiffs refer to as "toxic" carcinogens. (Pls.' Br. at 5.) However, the presence of NDMA in generic VCDs did not alter their clinical safety; nor did it have any impact on how the VCDs work—i.e., their pharmacokinetics or pharmacodynamics. (*See* TPP Trial Defs.' Omnibus Statement of Material Facts Not

in Dispute ("SUMF") ¶ 94, ECF No. 2571.) Indeed, as the FDA repeatedly made clear, any risk posed by the presence of a trace impurity in the medication was extremely low. (*See id.* ¶¶ 81-82.) Although the Court excluded portions of Defendants' expert Dr. Michael Bottorff's testimony, the Court did not preclude his opinion that "contaminated VCDs function the same in the human body as uncontaminated VCDs." (ECF No. 2581, at 11.) Moreover, Plaintiffs' own expert, Dr. Ramin Najafi, testified that a generic drug can be bioequivalent to the branded version without having an impurity profile that matches that of the reference listed drug. (SUMF Ex. 73, Deposition of Ron Najafi 20:9-10, 20:23-21:4, Feb. 3, 2022.) This evidence reflects, at the least, a disputed factual question as to whether the VCDs were therapeutic or generic equivalents, precluding summary judgment in Plaintiffs' favor.

Second, Plaintiffs argue that the "words in the July 27, 2017 email" demonstrate that ZHP knew that its representations were false. According to Plaintiffs, the email, which was originally written in Chinese (Pls.' SUMF Ex. 109), shows that the potential for nitrosamine formation in sartans was "known to be a common problem" (Pls.' Br. at 6). But "one internal email" (even if it had the meaning and import Plaintiffs ascribe to it) cannot suffice to establish—as a matter of law—that ZHP knowingly misrepresented or failed to disclose material safety information. *See Tershakovec v. Ford Motor Co.*, 546 F. Supp. 3d 1348, 1364-65

(S.D. Fla. 2021) ("one internal email" mentioning the possibility of "Limp Mode" on public roads is not "sufficient evidence such that any reasonable juror could find that Ford had knowledge that the [vehicles] would go into Limp Mode under normal driving conditions"), *aff'd in part, vacated in part, rev'd in part*, 79 F.4th 1299 (11th Cir. 2023) (granting summary judgment on omission-based fraud claims for lack of scienter).

In any event, as Plaintiffs acknowledge, the email is not even about valsartan API—the product in question. (Pls.' Br. at 6.) Rather, Mr. Lin's email addresses a hypothetical nitrosated impurity in the lab-scale production of Irbesartan, a different drug molecule from valsartan API. (*Id.*) In discussing that impurity, Mr. Lin references a patent, which is attached to his email, that notes the potential for the formation of "Valsartan Impurity K," another nitrosated impurity that can form when deacylated valsartan is quenched with sodium nitrite. (Pls.' SUMF Ex. 109.) It was this substance—Valsartan Impurity K formed by the quenching of deacylated valsartan—that Dr. Lin was actually suggesting the Irbesartan impurity resembled, not NDMA formed during the quenching step of the Zinc Chloride process. (Pls.' SUMF Ex. 24.) While Plaintiffs insist that the "words in the . . . email are clear" and support their theory of the case (Pls.' Br. at 6), the meaning of that document raises factual questions that are the jury's to decide.

This is all the more true in light of other evidence (ignored by Plaintiffs) that ZHP had no knowledge of the potential for nitrosamine formation in its valsartan-based manufacturing processes prior to 2018. Before submitting the proposed manufacturing changes at issue in this litigation, ZHP ran a number of tests on the possible effects from its changes, and none indicated that the formation of impurities would occur. (*See* SUMF ¶ 10 (quoting SUMF Ex. 16, ZHP01838512 at 517 (certified translation at 4) (noting that "[a]dding sodium nitrite quenching operation can effectively remove azide ions in the reaction solution, and basically will not cause negative effects on product quality")).) In addition, statements from the FDA confirm that the formation of NDMA and NDEA was not reasonably foreseeable prior to the FDA's analysis in 2018. For instance, in July 2018, the FDA stated that "the presence of NDMA was unexpected," and the FDA Commissioner reiterated just a month later that "[b]efore [the FDA] undertook [an] analysis, neither regulators nor industry fully understood how NDMA could form" during ZHP's manufacturing process. (*See* SUMF ¶¶ 61-63 (quoting SUMF Ex. 1, July 13 FDA News Release at 1; SUMF Ex. 64, August 2018 Gottlieb Statement at 4).) In short, as with the question of falsity, whether ZHP had knowledge of any purportedly misrepresented safety risk is a disputed issue in this case.

Third, Plaintiffs also argue that ZHP intended that "others rely on the misrepresentation," highlighting ZHP Executive Vice President Jun Du's statements

to the FDA that the change to the zinc chloride process is "what allowed ZHP to dominate the world market for valsartan." (Pls.' Br. at 7 (citing Pls.' SUMF ¶ 20).) But the statements plucked out of context by Plaintiffs merely reflect that one of the benefits of changing ZHP's manufacturing process was "cost reduction" (Pls.' SUMF Ex. 13), which says nothing about any "intent" to defraud anyone, much less the TPPs whose claims are the subject of the instant motion. *See, e.g.*, *First Valley Leasing, Inc. v. Goushy*, 795 F. Supp. 693, 701 (D.N.J. 1992) ("[B]ecause there is a fact question concerning the issue of whether defendant intended to defraud the plaintiff, the court must deny plaintiff's motion for summary judgment on the [New Jersey common-law] fraud claim.").

In any event, even assuming that Mr. Du's statements constituted competent evidence of scienter, there remains substantial other evidence in the record weighing against an inference of intentionality. For example, as ZHP communicated in its submission of Amendment-004 to the FDA, the primary purpose of adopting the Zinc Chloride process "was to reduce impurity A in valsartan" (SUMF ¶ 14 (quoting SUMF Ex. 19, Deposition of Linda Lin 209:2-210:5, May 5, 2021), and to address an "EHS [Environment, Health & Safety] concern" (*id.* ¶ 13 (quoting SUMF Ex. 18, PRINSTON00073102 at 104)). ZHP also noted that the substitution of zinc chloride for triethylamine hydrochloride as the applicable reagent provided satisfactory yields while lowering EHS and quality concerns. (*Id.* (citing SUMF Ex. 18,

PRINSTON00073102 at 108).) This evidence more than suffices to create a triable question as to ZHP's state of mind in changing its manufacturing process.

Fourth, Plaintiffs argue that "reasonable reliance cannot be disputed." (Pls.' Br. at 7.) According to Plaintiffs, "[n]o TPP would have been able to pay for the contaminated valsartan if the truth had been told because it would not have been sold." (*Id.*) But the pertinent question is not whether the VCDs would have been sold at all; rather, it is what (if anything) Plaintiffs and the other TPP subclass members relied on in making formulary or other decisions related to the medication. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, 2019 U.S. Dist. LEXIS 24063, at *427-28 (N.D. Ill. Feb. 14, 2019) (granting summary judgment to defendant on fraud claims asserted by a TPP because jury "could not find that MMO relied on [alleged safety representations] to make any formulary or utilization management decision regarding the drugs"). The record here is devoid of any evidence that Plaintiffs' assignors or any of the numerous TPP subclass members relied on any purported fraud (*see* SUMF ¶¶ 123-24), which is why ***ZHP*** is entitled to summary judgment, not Plaintiffs.

Fifth, Plaintiffs assert that they were "certainly damaged by paying for adulterated, contaminated valsartan"; "[t]he only question . . . is the calculation" of damages. (Pls.' Br. at 8.) However, as elaborated in Defendants' motion for summary judgment, Plaintiffs received exactly what they paid for—effective blood

pressure medication for their members—and therefore were not harmed. *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action Litig.*, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *9 (D.N.J. July 10, 2009) (granting motion to dismiss and rejecting theory of TPP injury where defendants "provide[d] their beneficiaries with the most effective treatment available"). Moreover, absent the VCDs, the TPPs would have had to pay for alternative forms of blood pressure medication, some of them much more expensive, or pay costs stemming from the complications of untreated hypertension, which would be more extensive still. (*See* SUMF ¶ 130.) Accordingly, Plaintiffs' argument on injury and damages is contrary to law, the record evidence and basic logic.

In sum, Plaintiffs' motion raises, at most, a series of factual questions that should be resolved by the jury; it does not come close to warranting the extraordinary step of deciding Plaintiffs' fraud claims in their favor before trial.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for partial summary judgment on fraud.

Dated: January 22, 2024

Respectfully submitted,

By: */s/ Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 22, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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